REMARKS

This responds to the Office Action for the parent application, mailed on June 12, 2006.

No claims are amended, canceled, or added; as a result, claims 1, 4, 7-22, and 25 are now pending in this application.

Applicant submits herewith a Request for Continued Examination so that the discussion presented below may be considered.

§102 Rejection of the Claims

The Examiner maintained the rejection of claims 1, 4, 7, 13, 14, 20, 21 and 25 under 35 U.S.C. § 102(b) as being anticipated by US 6,060,085 ('085) to Osborne or US 5,863,560 ('560) to Osborne (as evidenced by Russell, AFP, 2000).

The Examiner continues to base the anticipation rejection on a theory of inherency, stating that because the most common situation is a mixture of both inflammatory and non-inflammatory acne, '085 and '560, which teach the use of dapsone in treating inflammatory acne, inherently teach the claimed method of reducing non-inflammatory acne.

Applicant traverses the rejection and submits that the Examiner's theory of inherency is misapplied. This issue of inherency telescopes all of the Examiner's other arguments; thus, Applicant will focus on each of the arguments in the context of the overarching issue of inherency. First, however, it is Applicant's position that the patent law on inherency generally relies on a fundamental, but not articulated, presumption of actual use. Applicant submits that if the topical dapsone of Osborne had actually been used to treat inflammatory acne, the Examiner would be correct in stating that the Osborne dapsone inherently treated non-inflammatory acne. However, as has been discussed in the earlier amendments, there was no actual use of Osborne's topical dapsone in treating acne of any kind; therefore, inherency cannot attach.

Although the Federal Circuit has not specifically discussed the issue of actual use, there are two generally-applied principles present in the case law that show actual use is a prerequisite for inherency. The first principle is that anticipation attaches only if the alleged inherent feature

necessarily occurs each and every time the prior art composition or method is used (Donald S. Chisum, CHISUM ON PATENTS § 3.03[2][b], 2006). The second principle is that a newly discovered feature is inherent if the applicant claims the same use as described for a prior art composition or method but asserts patentability by additionally claiming the new feature of that composition or method.

In each of these two general principles of inherency law, the actual use of the method or composition is presumed. In the first situation, it would be impossible to conclude that a feature is inherent if the method or composition had never before been actually used, because of the requirement that this feature be present *every time the prior art method or composition is used.* In the second situation, the newly discovered feature would not have been discovered without the prior use of the prior art method or composition. Applicant therefore respectfully submits that this presumption of actual use of the prior art method or composition is a real and necessary element of inherent anticipation.

In the instant case, the dapsone of Osborne does not inherently reduce non-inflammatory acne, because topical dapsone was *never actually used* to treat any form of acne prior to Osborne '085 and '560, or indeed within '085 and '560. The unique formulation, comprising dissolved dapsone and microcrystalline dapsone, was merely applied to the skin of cadavers to test its permeation and retention abilities. It was not until the clinical studies of the instant invention that it was actually applied to living skin for use in acne treatment. Applicant stresses that this is not a question of enablement, as Applicant discusses below. Rather, the point is that it would be impossible for dapsone to inherently treat non-inflammatory acne if it had never before been applied to skin for use in treating acne of any kind, much less for use in treatment of acne. Therefore, because actual use is a real and necessary element of inherent anticipation as discussed above, inherent anticipation of the method for treatment of non-inflammatory acne by Osborne does not attach.

In the following passages, Applicant will address each of the Examiner's arguments in turn, and explain how each of these arguments fails because each is based upon inherent anticipation. Applicant also urges the Examiner to acknowledge that the patentability of a new use for an "old" or known composition is a statutory mandate that has been relied on by the

C.C.P.A. and the Federal Circuit. In particular, the use of the prior art Osborne dapsone formulation to treat non-inflammatory acne falls within this statutory mandate. "See 35 U.S.C. § 101 (2000), identifying as patentable 'any new and useful improvements' of a process, machine, manufacture, etc); *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure)." *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005).

In the first section of the rejection, the Examiner explicitly agrees with Applicant (page 3, line 5) that Osborne '085 and '560 do not disclose treatment of non-inflammatory acne. Osborne discloses only inflammatory acne. Nevertheless, the Examiner concludes that the method of reducing and treating non-inflammatory acne lesions with dapsone is inherent in '085 and '560 because nothing in '085 or '560 indicates that the acne described therein is not the commonly occurring form, consisting of a mixture of both inflammatory and non-inflammatory acne (evidenced in Russell). Further, Examiner states (page 6, line 3) that Applicant has not provided evidence that the dapsone of '085 and '560 does not inhibit non-inflammatory lesions.

Applicant respectfully reiterates that this inherency syllogism of the Examiner is based upon actual use. The most commonly occurring form of acne contains both inflammatory and non-inflammatory lesions. Nevertheless, this fact does not lead to the conclusion that Osborne's treatment of inflammatory lesions also inherently treats non-inflammatory lesions. Osborne's disclosure of dapsone to treat inflammatory acne does not, without actual use, establish that dapsone inherently treats non-inflammatory acne.

As articulated above, had Osborne actually treated inflammatory acne with his dapsone formulation, then the Examiner's inherency argument would be appropriate. However, neither Osborne nor anyone else actually treated inflammatory acne with topical dapsone before the clinical trials leading to the present invention were conducted.

Osborne tested dapsone only on the skin of cadavers in '085 and '560, and only for the purpose of determining permeation through the skin and retention on the skin's surface, not to assess its success in treating acne. Cadaver skin does not have acne. There was absolutely no actual use of dapsone to treat any type of acne, be it inflammatory or non-inflammatory, until the clinical studies of the current invention. Thus, it is no surprise that neither of the Osborne

patents discloses the failure of dapsone to treat non-inflammatory acne, because neither of the Osborne patents actually used or tested dapsone on acne of any kind.

The Examiner next states (page 6, line 7) that the present claims do not exclude the patient population having mixed forms of acne. This appears to be an invitation to amend the claims as such, and leads the Applicant to believe that the Examiner recognizes dapsone's ability to treat non-inflammatory acne as novel and patentable. However, it is Applicant's position that specifically excluding the treatment of mixed forms of acne from the claims would be inappropriate.

The Examiner argues (page 6, line 15) that the statement in Sykes, that topical antibiotics have "probably" no role in treating comedonal phase acne, does not lead to the conclusion or teach that antibiotics absolutely are not effective or do not treat non-inflammatory phase acne. In response to this argument, Applicant first directs the Examiner to the previously submitted Declaration under 37 C.F.R. 1.132 of Robert Lathrop, submitted in response to the Office Action dated 3/16/2004. As one of skill in the art, Mr. Lathrop provides evidence of the clinical and biological differences between inflammatory and non-inflammatory acne, stresses the corresponding differences in treatments for the two types, and states that he is surprised that the dapsone formulation of the instant invention successfully reduces black-head (non-inflammatory) acne, because *anti-microbial agents are not used for such treatment*. Mr. Lathrop states that with black-heads, physicians understand that because there is no microbial infection, anti-microbials are *counter-indicated* (page 4, lines 7-9). Physicians do not prescribe anti-microbials unless there is a demonstrated presence of a microbial infection. Mr. Lathrop also cites three internet articles to further support the content of his Declaration.

Second, Applicant notes that research scientists and physicians rarely use such extreme terms as "never" or "absolutely not" when describing their art; yet the Examiner is requiring such language in order to be convinced that one of skill in the art knows that topical antibiotics have no role in treating non-inflammatory phase acne. The state of the art is very clear in this regard, and the Examiner is encouraged to acknowledge the abundance of support for Applicant's position.

The Examiner further states (on page 7) that Applicant is apparently questioning the enablement or operability of the cited Osborne patents. Applicant respectfully submits that the Examiner has misunderstood the point of Applicant's arguments, confusing the "actual use" inherency argument with an enablement argument. The Examiner is presumably referring to the discussion from the bottom two paragraphs on page 7 through the top paragraph on page 8 of Applicant's previous response.

Enablement and inherency are separate and distinct issues. The enablement of Osborne '085 and '560 is clear and accurate. It is abundantly clear that Osborne's disclosure of dapsone to treat inflammatory acne *is* enabled, because inflammatory acne is caused by bacteria and dapsone is a well-known antibacterial agent. Osborne is not required to have actually run experiments or performed a process in order to obtain an enforceable patent claiming treatment of inflammatory acne caused by *P. acnes* (M.P.E.P. 2138.05). However, actual use of the prior art method for treatment of inflammatory acne is needed in order for inherency of the treatment of non-inflammatory acne to be found. It cannot be said that dapsone inherently reduces non-inflammatory acne, because dapsone was never applied to any kind of living skin condition prior to the instant invention. Dapsone was only tested on the skin of cadavers in '085 and '560 patents, and only for the purpose of determining permeation through the skin and retention on the skin's surface. There was absolutely no actual use of dapsone to treat any type of acne (inflammatory or non-inflammatory), or any other skin ailment, until the clinical studies of the current invention.

The Examiner cites case law on page 8 in support of her position. Applicant first points out that the quote from the *Atlas Powder* case concerns a composition claim, not a method claim. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old *composition* patentably new to the discoverer" (emphasis added). Thus, *Atlas Powder* is inapposite to the instant case. Applicant is not attempting to claim the dapsone composition itself, but rather methods of using it.

The Examiner has also cited *In re May*, stating that "when the claim recites using an old composition or structure and the 'use' is directed to a result or property of that composition or

structure, then the claim is anticipated." Applicant points out that in *In re May*, the 'use' at issue was identical to the use practiced in the prior art. Specifically, the prior art and the claim at issue both recited a method for effecting analgesia by administering a certain compound. The claim at issue in *May* also recited the additional feature of non-addictiveness. The *May* appellants had discovered the previously unknown property of non-addictiveness, but the claimed use was the same as the prior art use.

The *In re May* case is thus also factually inapposite to the instant case. Had Applicant in the instant case claimed the use of dapsone to treat inflammatory acne (as is described in Osborne), with the additional feature of it not stinging or not irritating the skin, for example, the Examiner's use of *In re May* might have been applicable. However, this is not the case. Applicant claims a different use altogether from the treatment of inflammatory acne of Osborne: the treatment of the art-appreciated, separate and distinct ailment of non-inflammatory acne. Additionally, Applicant points out that there was actual use of the methods within *In re May*, in which the C.C.P.A. found anticipation of the method claims at issue.

In citing *In re Crish* and *In re Best*, the Examiner has pointed out that the claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. Applicant responds that the Examiner is merely repeating the first and second general principles of inherency, as discussed above. Applicant notes that these cases nevertheless remain inapposite to the instant case. In *In re Crish*, the applicant had claimed the nucleotide sequence of a promoter that had been previously identified, used in plasmid constructs, and characterized by restriction enzyme digest. The applicant had simply further characterized the promoter by sequencing the DNA, and the Federal Circuit found anticipation. Thus, the applicant in *Crish* attempted to claim a composition already described and actually used according to the prior art. This is ordinary anticipation, rather than inherent anticipation.

In contrast, the present Applicant claims a distinct method of use of a compound, not the compound itself or a further-characterized portion of that compound. Moreover, no actual use occurred in the present situation, in contrast to that of *Crish*. Finally, Applicant again stresses

that new uses of old compounds are patentable, as statutorily mandated and upheld by the Federal Circuit.

The *In re Best* case is misapplied to the instant case as well. The *Best* claims at issue were directed to zeolitic molecular sieve catalyst compositions and a process for producing them. The claims described method steps for producing the zeolitic catalyst, including a crucial cool-down step that had not been described in the otherwise-identical prior art method. The C.C.P.A. held the *Best* claims were anticipated because the C.C.P.A. concluded that a prior art zeolitic catalyst would have necessarily been cooled to facilitate subsequent handling.

Applicant stresses the fact that the prior art method steps in the *In re Best* case were *actually performed.* Without the actual use in the prior art, it would have been impossible to determine whether the claims at issue were anticipated by the prior art methods. This again differs from the instant case, wherein the methods described in Osborne were never actually performed. Dapsone was never actually applied to the skin of living persons, much less to skin having acne.

Applicant directs the Examiner to another well-known inherency case, *In re Cruciferous Sprout Litigation* (301 F.3d 1343 (Fed. Cir. 2002)). The claims at issue were directed to methods of preparing cruciferous plants, whereby the sprouts were harvested prior to the two-leaf stage to obtain the benefits of high levels of anti-carcinogenic glucosinolates therein. The *Cruciferous* applicants had discovered that plants harvested at this stage contained higher levels of glucosinolates than plants harvested after this stage. The Federal Circuit found the claims anticipated, because even though the prior art did not expressly or inherently disclose this property of the plants harvested at the two-leaf stage, numerous prior art references identified the same sprouts as suitable for eating. The court stated, "Brassica cannot credibly maintain that no one has heretofore *grown and eaten* one of the many suitable cultivars identified by its patents." (emphasis added). Id. at 1351. Here again, the Federal Circuit relies upon the fact that the method of the prior art was *actually performed.* It is the actual prior art performance of the steps of the claims, in the context disclosed by the claims, that is crucial in an inherency analysis of anticipation.

The foregoing arguments show that because the method steps of treating inflammatory acne with dapsone were never actually carried out on any type of acne, nor even on living skin prior to the clinical studies of the current invention, the dapsone of Osborne does not inherently reduce non-inflammatory acne lesions. Withdrawal of this rejection is respectfully requested.

§103 Rejection of the Claims

Claims 8-12, 15-19 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,060,085 in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of US 6,200,964 to Singleton et al OR over US 5,863,560 ('560) in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of Russell and US 6,200,964 to Singleton et al.

The Examiner has again carried over the inherency argument from the § 102(b) rejection above, that the ability to treat non-inflammatory acne is inherent to the composition of dapsone of Osborne, and thus the Russell and Singleton disclosures of cream, lotion, spray, suspension, or ointment formulations in combination with Osborne make the instant invention obvious to one of skill in the art. The Examiner states that one of skill would prepare the compositions depending on skin type and solubility of the compound, with an expectation to achieve the desired treatment of acne lesions (both types).

First, the Examiner is requested to note that the inherency doctrine has no place in the determination of the obviousness of a new use of an old compound. In *In re Shetty*, 195 USPQ 753 (C.C.P.A. 1977), the issue was the obviousness of a method comprising administration of certain adamantane derivatives to curb appetite, in view of prior art disclosing that analogous adamantanes, given in the same doses, acted as antiviral agents. In reversing the Board's holding of obviousness, the Court stated:

> The Patent Office has failed to show a reasonable expectation, or some predictability, that [Appellants'] compound would be an effective appetite suppressant if administered in the dosage disclosed by [the prior art]. The mere hindsight assertion that corresponding dosages render appellant's method obvious is untenable. Prior to appellant's disclosure, none of the adamantine compounds in any of the references before us suggested use, much less a dosage, for curbing appetite.

Id. at 756.

More recently, the Federal Circuit distinguished the concepts of "inherency" and "obviousness":

> The Board stated that it is inherent in Dillon's compositions that they would reduce particulate emissions, that Dillon "merely recited a newly discovered function inherently possessed" by the prior art. The courts have not upheld arguments based on "inherent" properties when there is no supporting teaching in the prior art. Inherency and obviousness are distinct concepts. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555, 220 USPQ 303, 314 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (C.C.P.A. 1966) ("the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."). When the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, the PTO must produce supporting references. *Yates*, 663 F.2d at 1057, 211 USPQ at 1151.

In re Dillon, 13 USPQ2d 1335, 1348 (Fed. Cir. 1989), *rev'd on other grounds*, 16 USPQ2d 1897 (Fed. Cir. 1990).

Additionally, Applicant points out that M.P.E.P. § 2141.02 (V) states: "Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). Thus, withdrawal of the 35 U.S.C. § 103 rejection is respectfully requested.

In summary, the Examiner has relied on a theory of inherency for each of her arguments in rejecting the claims of the instant application. The entire case stands or falls on whether the dapsone of Osborne '085 and '560 inherently possesses the ability to reduce non-inflammatory acne. The Examiner's fundamental inherent anticipation argument carries over to her other arguments. Without the initial presumption of inherency, each of the Examiner's arguments fail.

It is Applicant's position that the Examiner has incorrectly applied the doctrine of inherency. Applicant stresses that all of the ancillary arguments, in which the Examiner presumes inherency, favor Applicant if the Examiner's initial inherency argument is overcome. Applicant's fundamental argument against inherency is that because the dapsone method of

Osborne '085 and '560 was never *actually used* to treat any kind of skin condition in a living being, be it inflammatory acne or non-inflammatory acne, this method *cannot* be said to inherently possess activity useful in the treatment of non-inflammatory acne. Any other conclusion would require abolishment of the well-established mandate of the patentability of a new use of a known compound. Thus, Applicant respectfully requests reconsideration of this position.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested.

The Examiner is invited to telephone Applicant's attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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